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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/446,677 03/24/00 BIRKELUND

S BIRKELUND=1

001444 HM12/0927
BROWDY AND NEIMARK, P.L.L.C.
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EXAMINER

SHAHNAN-SHAH.K

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

09/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/446,677

Applicant(s)

BIRKELUND ET AL.

Examiner

Khatol S Shannan-Shah

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-13, 15 and 16 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I: Claims 1-3, 6 and 8, are drawn to antibodies against outer membrane of Chlamydia pneumoniae and their method of detection.

Group II: Claims 4 and 9, are drawn to a nucleic acid fragment derived from Chlamydia pneumoniae and a diagnostic kit comprising said fragment.

Group III: Claims 5,7,10-12 are drawn to a protein derived from Chlamydia pneumoniae, a diagnostic kit comprising said protein, a composition comprising said protein and use of said protein for diagnosis of Chlamydia pneumoniae.

Group IV: Claims 13,15-16 are drawn to a method of immunization against Chlamydia pneumoniae.

2. The inventions listed as groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same technical features for the following reasons:

Group I and group III lacks novelty under PCT Article 33(2) as being anticipated by Melgosa et al. (FEMS Microbiology Letters Vol. 112, No. 2, pp. 199-204, September 1993) and Kuroiwa et al. (EP 0 699 688 A2).

Melgosa et al. teach detecting antibodies against outer membrane complex proteins of *Chlamydia pneumoniae*. They teach Western blots and immunoassays. (see pages 200 and 201). Kuroiwa et al. disclose antibodies, which have specific reactivity to the major outer membrane protein of *Chlamydia pneumoniae* (see abstract and claims). They also teach diagnostic reagents and kit for detecting *Chlamydia pneumoniae*.

Group I is the main invention in this application and lacks novelty, therefore the other claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form single inventive concept.

Election

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- a) If applicants elect group I, then there are additional election of species.

Please elect one of SEQ ID Numbers from SEQ ID 1-24.

- b) If applicants elect group II, then there are additional election of species.

Please elect one of SEQ ID Numbers from SEQ ID 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, or 23.

- c) If applicants elect group III, then there are additional election of species.

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Please elect one of SEQ ID Numbers from SEQ ID 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, or 24.

d) If applicants elect group IV, then there are additional election of species.

Please elect one of SEQ ID Numbers from SEQ ID 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, or 24.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Groups I-IV are drawn to a plurality of disclosed patentably distinct polypeptides comprising materially different amino acid sequences as evidence by separate SEQ ID Numbers. The separate polypeptides bear distinct structural or biochemical properties. Therefore, **each disclosed patentably distinct polypeptide is considered a separate technical feature.**

Groups I- II are drawn to a plurality of disclosed patentably distinct polynucleotides comprising materially different nucleotide sequences as evidence by separate SEQ ID Numbers. The separate polynucleotides bear distinct structural or biochemical properties. Therefore, **each disclosed patentably distinct polynucleotide is considered separate technical feature.**

4. Should applicants traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing which special technical features as exemplified by separate SEQ ID Numbers are obvious variants of each other or clearly admit on the record which inventions are obvious variants of each other. If the inventions are deemed obvious variants of each other, then if the examiner finds one of the inventions unpatentable over the prior art, the evidence submitted by applicant or admission of


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record by applicant may be used in a rejection under 35 U.S.C. §103(a) of the other invention.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached on 7:30 AM - 4 PM from Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

 9/28/01

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner


LYNETTE R. F. SMITH
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